UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ANNE de LACOUR *individually and on behalf of all others similarly situated* and ANDREA WRIGHT *individually and on behalf of all others similarly situated,*

Plaintiff,

v.

COLGATE-PALMOLIVE CO. and TOM'S OF MAINE INC.,

Defendants.

No. 16-CV-8364 (RA)

OPINION AND ORDER

RONNIE ABRAMS, United States District Judge:

Plaintiffs filed this lawsuit against two companies—Colgate Palmolive Co. and Tom's of Maine Inc.—that use the word "natural" in advertising their personal-care products, including deodorant and toothpaste. Compl. ¶ 1(Dkt. 1); Am. Compl. ¶¶ 1, 15, 17 (Dkt. 8). In their Amended Complaint, Plaintiffs assert that the Defendants' products are unnatural because they contain "synthetic and highly chemically processed ingredients." Am. Compl. ¶¶ 16, 18, 23. Plaintiffs claim that Defendants' advertising was a breach of an express warranty and was false and misleading in violation of various state statutes. *Id.* ¶¶ 46–132. Defendants now move for a stay under the doctrine of primary jurisdiction, arguing that the Court should stay this case until the U.S. Food and Drug Administration can weigh in on the meaning of "natural." *See* Dkt. 32, 33. For the reasons below, Defendants' motion is denied.

BACKGROUND

In 1993, the FDA published guidance on the meaning of the term "natural" in the food context. *See Food Labeling*, 58 Fed. Reg. 2302-01, 1993 WL 1540 (Jan. 6, 1993). Pursuant to

that guidance, the term "natural" means that "nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food." *Id.* at 2407. In November 2015, the FDA began a related investigation by requesting comment on the "Use of the Term 'Natural' in the Labeling of Human Food Products" in anticipation of promulgating a rule on the subject. *See* 80 Fed. Reg. 69905-01, 2015 WL 6958210 (Nov. 12, 2015). The FDA sought commentary on various questions, including whether the agency should further define the term "natural" at all. *See id.* at 69908. The agency's substantive questions to commenters focused on issues specific to the food context, such as whether consumers would confuse the term "natural" with the term "healthy" and whether genetically engineered foods should be considered natural. *Id.* at 69908-09. The comment period closed on February 10, 2016. *See id.* at 69905. In the nearly two years since then, the FDA seemingly has neither responded to comments nor published a definition of the word "natural" in any context.

In late 2016, Plaintiffs filed this lawsuit asserting among other things that Defendants' use of the word "natural" in advertising their personal-care products is misleading. In the Amended Complaint, Plaintiffs support their understanding of the term "natural" in part by referring to the FDA's 1993 ruling on the term's meaning in the food context. *See* Am. Compl. ¶ 25. According to Plaintiffs, Defendants' products contain synthetic and chemically processed ingredients—allegedly including aluminum chlorohydrate, ascorbic acid, glycerin, and potassium nitrate, among others—that Plaintiffs say are not natural. *Id.* ¶ 27.

Defendants now move for a stay under the doctrine of primary jurisdiction, arguing that the Court should stay this case until the FDA can weigh in on the meaning of the word "natural" based on the comments it requested in November 2015. *See* Dkt. 32, 33. Plaintiffs have opposed

the motion, *see* Dkt. 35, and Defendants have replied, *see* Dkt. 40.

LEGAL STANDARD

Federal courts developed the doctrine of primary jurisdiction "to ensure that courts and agencies with concurrent jurisdiction over a matter do not work at cross-purposes." *Fulton Cogeneration Assocs. v. Niagara Mohawk Power Corp.*, 84 F.3d 91, 97 (2d Cir. 1996). Although the scope of the doctrine is "relatively narrow," courts may defer to agencies to "maintain[] uniformity in the regulation of an area entrusted to a federal agency" and to "utiliz[e] administrative expertise" on technical questions. *See Ellis v. Tribune Television Co.*, 443 F.3d 71, 82, 91 (2d Cir. 2006). "Despite its name," the doctrine is prudential rather than jurisdictional. *See Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 324 (S.D.N.Y. 2017).

"No fixed formula exists for applying the doctrine of primary jurisdiction" and cases are analyzed "on a case-by-case basis." *Ellis*, 443 F.3d at 82 (citations and internal quotation marks omitted). Even so, the Second Circuit has identified four guiding factors that indicate whether the primary-jurisdiction doctrine applies: "(1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise; (2) whether the question at issue is particularly within the agency's discretion; (3) whether there exists a substantial danger of inconsistent rulings; and (4) whether a prior application to the agency has been made." *See id.* at 82–83. If the Court finds that these factors weigh in favor of allowing an agency to address the relevant questions first, the Court may stay or dismiss the case. *See Canale*, 258 F. Supp. 3d at 326.

DISCUSSION

Defendants argue that all four *Ellis* factors weigh in favor of granting a stay while the FDA addresses the definition of "natural." *See* Dkt. 33. For the reasons discussed below, however, the

purposes of the primary-jurisdiction doctrine would not be served by deferring to the FDA and a balance of the *Ellis* factors weighs against the imposition of a stay at this time.

As to the first factor, Defendants contend that defining what counts as "natural" is a highly technical determination falling particularly within the FDA's expertise. In 2015, the Ninth Circuit seemed to agree with Defendants, noting that "[d]etermining what chemical compounds may be advertised as natural on cosmetic product labels is a particularly complicated issue that Congress has committed to the FDA[.]" *See Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 761 (9th Cir. 2015) (internal quotation marks omitted). Courts in this District have sometimes agreed, but they have also consistently held that the main issue in this case—namely, whether advertising is deceptive or misleading to consumers—is squarely within judges' expertise. *See, e.g.*, *Canale*, 258 F. Supp. 3d at 325 (gathering cases). Thus, "[c]ourts are split as to whether the issues presented by . . . 'all natural' claims are more within the conventional expertise of judges or whether they involve technical or policy considerations within the FDA's particular field of expertise." *In re KIND LLC "Healthy & All Natural" Litig.*, 209 F. Supp. 3d 689, 694 (S.D.N.Y. 2016). Given this split, the Court "is reluctant to declare" the issues in this case to be "outside the conventional wisdom of judges" and notes that "judges and triers of fact regularly address complex scientific issues absent regulatory guidance." *Id.* at 695. The first factor, therefore, "does not weigh in favor of the FDA's primary jurisdiction." *Id.*; *cf. Canale*, 258 F. Supp. 3d at 325 (holding that the first factor was neutral).

The application of the second factor—"whether the question at issue is particularly within the agency's discretion," *see Ellis*, 443 F.3d at 83—is more straightforward here. The FDA has the statutory authority to prohibit labels that are "false or misleading in any particular." 21 U.S.C. § 343. Thus, as courts in this District have consistently held, the FDA has the discretion to decide

what foods or personal-care products can honestly be labeled as "natural." *See, e.g.*, *In re KIND LLC*, 209 F. Supp. 3d at 695; *Goldemberg v. Johnson & Johnson Consumer Companies, Inc.*, 8 F. Supp. 3d 467, 477 (S.D.N.Y. 2014); *see also Canale*, 258 F. Supp. 3d at 325. Plaintiffs respond that the FDA is not the only source of meaning for the term "natural" in this case. According to Plaintiffs, the Court can use other sources, like dictionaries, to determine what the word means and whether it was misleading. That argument, however, is fundamentally about whether judges can resolve the issue here without the technical expertise of the agency, which in essence implicates the first factor. The second factor, meanwhile, focuses on whether Congress has specifically delegated the applicable decision-making authority to the agency. *See generally Ellis*, 443 F.3d at 84–86. As relevant here, Congress has done so. Thus, the second factor weighs in favor of a stay.

Under the third *Ellis* factor, courts are more likely to defer to agencies if there is "a substantial danger of inconsistent rulings." *Id.* at 83. "Courts should be especially solicitous in deferring to agencies that are simultaneously contemplating the same issues." *Id.* at 88. Defendants assert that this factor weighs in favor of granting a stay because there is a chance that the FDA (by publishing a rule) and other courts (in at least three other pending cases that Defendants contend are nearly identical to this one) will issue inconsistent rulings regarding the definition of the word "natural."

As an initial point, the fact that other courts may disagree with this Court on the definition of "natural" is not decisive here. "Instead, the danger of inconsistency on which the Court focuses is the danger that the FDA may issue guidance that conflicts" with the Court's ruling. *Elkind v. Revlon Consumer Prod. Corp.*, No. 14-CV-2484 JS AKT, 2015 WL 2344134, at *10 (E.D.N.Y. May 14, 2015); *see also Ellis*, 443 F.3d at 88; *Goldemberg*, 8 F. Supp. 3d at 477. Moreover,

although "conflicting results in separate cases are a common concern, conflicts arising within the *same* case"—at the judicial and agency levels—"are especially problematic." *Ellis*, 443 F.3d at 88 (emphasis in original). Here, there is less of a concern about a conflict within the same case because the FDA is considering whether to publish a generally applicable rule rather than adjudicating a specific issue between the parties in this case.

Defendants argue, however, that the FDA's potential rule could conflict with a ruling by this Court. Specifically, Defendants note that the FDA's 2015 request for comments included at least one general question that could apply to this case: namely, whether "the manner in which an ingredient is produced or sourced" (*e.g.*, whether it is synthetic) should impact the definition of "natural." *See* 80 Fed. Reg. at 69905. But the FDA's 2015 request for comments was plainly limited to the use of the word "natural" in food labeling. *See id.* at 69905–09. The publication's title recognized that limitation, and its substance focused on consumer concerns about the word "natural" that have no bearing on personal-care products, such as whether foods can be natural when they are genetically engineered, have multiple ingredients, or are not raw agricultural commodities. *Id.* at 69908. Although this case does not involve food products, there is indeed some chance that an FDA definition of the term "natural" in that context might be somewhat instructive here. That chance, however, does not amount to a "substantial danger" of a truly inconsistent ruling.[1] Thus, this factor weighs against granting the stay.

The fourth factor—"whether a prior application to the agency has been made," *Ellis*, 443

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[1] Defendants also assert that Plaintiffs should be barred from arguing that the FDA's future ruling is irrelevant to this one because Plaintiffs themselves rely on the FCC's 1993 ruling on the definition of "natural" in the food context in their Complaint. *See* Defs' Reply Mem. at 1. The question here, however, is not whether the FDA's future ruling may be helpful at all, but whether its promulgation may lead to a "substantial danger of inconsisten[cy]." *See Ellis*, 443 F.3d at 82.

F.3d at 83—similarly weighs against granting a stay in this case. A "prior application" exists when the agency is conducting an ongoing investigation, has initiated proceedings based on citizen petitions, or is otherwise currently reviewing the relevant questions. *See Canale*, 258 F. Supp. 3d at 325; *In re KIND*, 209 F. Supp, 3d at 696; *Town of Riverhead v. CSC Acquisition-NY, Inc. (Cablevision)*, 618 F. Supp. 2d 256, 270 (E.D.N.Y. 2009). This factor weighs in favor of a stay when the relevant issues in a case "may already be pending before the agency." *See Demmick v. Cellco P'ship*, No. CIV.A. 06-2163 JLL, 2011 WL 1253733, at *6 (D.N.J. Mar. 29, 2011). Defendants argue that the FDA is reviewing the relevant questions here based on its 2015 request for comments. As explained above, however, that consideration is not directly relevant to this case. *Cf. Frontier Tel. of Rochester, Inc. v. USA Datanet Corp.*, 386 F. Supp. 2d 144, 150 (W.D.N.Y. 2005) (holding that the fourth factor weighed in favor of granting a stay where the agency was seeking comments on "the[] very" issues in the case and intended to issue a relevant and comprehensive set of rules). Defendants also note that the FDA received two comments in response to its 2015 request that implicate personal-care products and suggest that the FDA promulgate definitions for the word "natural" as used in that context. *See* Defs' Mem. at 8 n.3 (Dkt. 33). These comments, however, are neither formal petitions to the FDA nor indications that the agency is in fact going to consider the question of how the word "natural" may be used on non-food products. Thus, this factor weighs against granting the stay.

The parties and the courts within this Circuit are seemingly split as to whether the Court should also "analyz[e] the potential advantages of applying the [primary-jurisdiction] doctrine against the potential costs," including undue delay. *See Ellis*, 443 F.3d at 90–91 (noting that the Second Circuit "ha[s] sometimes refused to" apply the doctrine when "agency referral would result in undue delay," but also remarking that the Second Circuit has "noted that . . . judicial economy

should not be considered" under Supreme Court precedent). If we were to consider judicial economy, it would further weigh against granting the stay. In the nearly two years since the comments were due, the FDA has given no indication that it will issue a rule on the use of the term "natural" in the food context any time in the near future, and there is no reason to think that will change. Moreover, the relative benefit of any ultimate decision—which will likely be relevant only by analogy to this case—is not worth the potential wait. By proceeding, there is little danger that the Court will be "work[ing] at cross-purposes" with the FDA. *See Fulton Cogeneration Assocs.*, 84 F.3d at 97. Thus, upon balancing the *Ellis* factors and considering the purposes of the primary-jurisdiction doctrine in light of the circumstances of this case, the Court finds that a stay is inappropriate at this time.

CONCLUSION

For the foregoing reasons, Defendants' motion for a stay is denied. The Clerk of Court is respectfully directed to terminate the motion at Dkt. 32.

SO ORDERED.

Dated: December 22, 2017
New York, New York

Ronnie Abrams
United States District Judge